## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Whittle, et al.

Serial No.:

To be assigned

Filed:

Concurrently Herewith

For:

PHARMACEUTICAL FORMULATIONS

Date: January 30, 2004

Mail Stop PATENT APPLICATION Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

Attached is a copy of one form PTO-1449 as filed in parent application serial number 10/434,259, with the Attorney Docket Number of the parent application struck through and the Attorney Docket Number of the above-referenced application written in.

A copy of each of the references above has been submitted to, or cited by, the Examiner in the parent application and is not provided herewith.

It is requested that all of these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.56 and Section 609 of the MPEP. No fee is believed due; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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Clara R. Beard

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office  LIST OF DOCUMENTS CITED BY APPLICANT					Attorney Docket Number -5573-115IP7CT3- 5573-115IP7CT7		Serial No. To Be Assigned	
	ПI	se several sheets is	f necessary)					
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Examiner Initial		Document Number	Date	N	ame	Class	Subclass	Filing Date if Appropriate
	1.	4,128,658	12/05/78	Price et al.		424	285	
	2.	4,255,431	03/10/81	Junggren et al	l	424	263	
	3.	4,279,819	07/21/81	Price et al.		260	326.5 S	
	4.	4,337,257	06/29/82	Junggren et al		424	263	
	5.	4,508,905	04/02/85	Junggren et al		546	271	
	6.	4,555,518	11/26/85	Rainer		514	338	
	7.	4,596,795	06/24/86	Pitha		514	58	
	8.	4,612,378	09/16/86	Bosshard et a		548	170	
	9.	4,620,008	10/28/86	Brändström et	al.	546	271	
	10.	4,628,098	12/09/86	Nohara et al.		546	271	-
	11.	4,636,499	01/13/87	Brändström et	al.	514	222	
	12.	4,725,691	02/16/88	Brändström et	al.	546	172	
	13.	4,727,064	02/23/88	Pitha		514	58	
	14.	4,738,974	04/19/88	Brändström		514	338	
	15.	4,753,955	06/28/88	Matsuishi et a	l	514	338	
<del></del>	16.	4,772,619	09/20/88	Adelstein et al		514	338	
	17.	4,777,172	10/11/88	Ife et al.		514	234.5	
<del></del>	18.	4,786,505	11/22/88	Lovgren et al.		424	468	
	19.	4,808,596	02/28/89	Matsuishi et a	l	514	303	
<del></del>	20.	4,820,708	04/11/89	Ife et al.		514	232.8	
<del></del>	21.	4,840,799	06/20/89	Appelgren et a	ıl.	424	493	
	22.	4,853,230	08/01/89	Lovgren et al.		424	466	
	23.	5,021,443	06/04/91	Bru-Magniez	et al.	514	394	
	24.	5,045,321	09/03/91	Makino et al.		424	475	
	25.	5,070,101	12/03/91	Kaminski		514	399	

	Pate OF DC	U.S. Department and Trademark	Office ED BY APPLI	Attorney Docket Number  5573 115IP7CT3  \$573-115 IP7CT 7		Serial No. To Be Assigned		
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	<u>,-</u>		U. S. P.	ATENT DOCUM	MENTS (Cont'd	)		
Examiner Initial		Document Number	Date	N	ame	Class	Subclass	Filing Date if Appropriat
	26.	5,075,323	12/24/91	Fain et al.		514	338	
	27.	5,093,132	03/03/92	Makino et al.		424	475	
	28.	5,093,342	03/03/92	Tomoi et al.		514	328	
	29.	5,096,893	03/17/92	Pitha et al.		514	58	
	30.	5,106,863	04/21/92	Hajos et al.		514	395	
	31.	5,124,158	06/23/92	Ruwart et al.		424	449	
	32.	5,178,867	01/12/93	Guittard et al.		424	473	
	33.	5,196,205	03/23/93	Borody		424	653	
	34.	5,204,118	04/20/93	Goldman et al		424	489	
<del></del>	35.	5,206,025	04/27/93	Courteille et a	1.	424	439	
	36.	5,219,870	06/15/93	Kim		514	338	
	37.	5,232,706	08/03/93	Palomo Coll		424	475	
	38.	5,244,670	09/14/93	Upson et al.		424	439	
	39.	5,246,714	09/21/93	Dahlinder et a	1.	424	497	
	40.	5,288,506	02/22/94	Spickett et al.		424	498	
	41.	5,294,439	03/15/94	Yamasaka et a	ıl.	424	78.01	
	42.	5,294,629	03/15/94	Machinami et	al.	514	366	
	43.	5,304,540	04/19/94	Blackburn et a	ıl.	514	2	
	44.	5,352,688	10/04/94	Kaminski		514	357	
	45.	5,362,424	11/08/94	Lee et al.		264	4.3	
	46.	5,374,730	12/20/94	Slemon et al.		546	271	
	47.	5,385,739	01/31/95	Debregeas et a	al.	424	494	
	48.	5,386,032	01/31/95	Brändström		546	271	
	49.	5,391,752	02/21/95	Hoerrner et al.		546	271	
	50.	5,399,700	03/21/95	Min et al.		546	271	
			<u> </u>					

## FORM PTO-1449 U.S. Department of Commerce Attorney Docket Number Serial No. Patent and Trademark Office -5573-115IP7CT3 To Be Assigned 5573-115 IPTCTS LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary) Applicants: Whittle et al. Filing Date Concurrently herewith Group: N t vet known U. S. PATENT DOCUMENTS (Cont'd) Examiner Document Filing Date Initial Number Date Name Class Subclass Appropriate 51. 5,417,980 05/23/95 Goldman et al. 464 424 52. 5,433,959 07/18/95 Makino et al. 424 475 53. 5,476,669 12/19/95 Borody 424 653 54. 5,508,041 04/16/96 Lee et al. 424 451 55. 5,514,660 05/07/96 Zopf et al. 514 25 56. 5,518,730 05/21/96 Fuisz 424 426 57. 5,536,735 07/16/96 Takechi et al. 514 338 58. 5,571,811 11/05/96 Heeres et al. 514 252 59. 5,578,732 11/26/96 Kato et al. 546 273.7 60. 5,582,837 12/10/96 Shell 424 451 61. 5,589,491 12/31/96 Nakanishi et al. 514 338 62. 5,599,794 02/04/97 Eek et al. 29 514 63. 5,616,593 04/01/97 Patel et al. 514 321 64. 5,620,964 04/15/97 Roth et al. 514 53 65. 5,622,717 04/22/97 **Fuisz** 424 488 66. 5,629,305 05/13/97 Eek et al. 514 199 67. 5,633,244 05/27/97 Eek et al. 514 199 68. 5,635,520 06/03/97 Uda 514 338 69. 5,637,592 06/10/97 Heeres et al. 514 252 70. 5,639,478 06/17/97 Makino et al. 424 475 71. 5,639,754 06/17/97 Heeres et al. 514 252 72. 5,650,411 07/22/97 Heeres et al. 514 252 73. 5,651,987 07/29/97 Fuisz 424 488 74. 5,656,286 08/12/97 Miranda et al. 424 449

75.

76.

6,262,085

6,262,086

07/17/01

07/17/01

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Whittle, et al.

Whittle, et al.

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	Pate	U.S. Department on and Trademark OCUMENTS CIT	Office	Attomey Docket Number <del>5573-115IP7CT</del> 3 <b>5573-115 2-P 7C 7 7</b>		Serial No.  To Be  Assigned		
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	,-	•			Applicants:	Whittle et a	ıl.	
		<del></del>			Filing Date	Concurrent	ly herewith	Group: Not
	77.	6,268,385	07/31/01	Whittle, et al.		514	338	08/24/00
	78.	5,665,730	09/09/97	Senn-Bilfinge	r et al.	514	300	
	ļ	<del> </del>						·
Examiner Initial		Document Number	Date	Na	ame	Class	Subclass	Filing Date if Appropriate
	79.	5,670,932	09/23/97	Kizima	·	340	384.6	
······································	80.	5,686,588	11/11/97	Yoo	<del></del>	536	13.3	
	81.	5,693,818	12/02/97	Von Unge		546	273.7	
	82.	5,710,156	01/20/98	Heeres et al.		514	255	
	83.	5,714,504	02/03/98	Lindberg et al		514	338	
	84.	5,719,161	02/17/98	Rainer		514	300	
	85.	5,728,700	03/17/98	Heeres et al.		514	252	
	86.	5,731,002	03/24/98	Olovson et al.		424	484	
· · · · · · · · · · · · · · · · · · ·	87.	5,753,630	05/19/98	Zopf et al.		514	25	
	88.	5,766,622	06/16/98	Nelson		424	440	
	89.	5,776,765	07/07/98	Graham et al.		435	280	
	90.	5,811,426	09/22/98	Heeres et al.		514	252	
<del></del>	91.	5,811,547	09/22/98	Nakamichi et a	al.	540	589	
<del></del>	92.	5,817,338	10/06/98	Bergstrand et a	al.	424	468	
	93.	5,840,552	11/24/98	Holt et al.		435	118	
	94.	5,846,562	12/08/98	Yanai et al.		424	451	
<del></del>	95.	5,859,030	01/12/99	Kohl et al.		514	338	
	96.	5,877,192	03/02/99	Lindberg et al.		514	338	
<del></del>	97.	5,916,904	06/29/99	Sato et al.		514	338	
	98.	5,929,244	07/27/99	Von Unge		546	273.7	
	99.	5,948,789	09/07/99	Larsson et al.		514	299	

FORM PTO 1440	II C Deserted	•£C•==					Serial No.	
Pat	FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office  LIST OF DOCUMENTS CITED BY APPLICANT					Attorney Docket Number <del>5573-115IP7CT3 -</del> <b>5573-115 IP7CT7</b>		
LIST OF D						•	Assigned	
(L	Jse several sheets if	necessary)						
				Applicants:	Whittle et a	ıl.	T	
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<del></del>		FORE	IGN PATENT I	OCUMENTS			-	
	Document Number	Date	Со	untry	Class	Subclass	Translation Yes   No	
100.	0124495 A2	11/07/84	EPO		C07D	401/12	х	
101.	61007281 A2	01/13/86	JAPAN		C07D	513/14	X (Abstract)	
102.	0166287 B1	01/02/86	EPO		C07D	401/12	Х	
103.	0171372 A1	02/12/86	ЕРО		C07D	513/14	х	
104.	61205211	09/11/86	JAPAN		A61K	031/44	X (Abstract)	
105.	0197013 A1	10/08/86	EPO		C07D	401/12	X	
106.	61271259	12/01/86	JAPAN		C07C	93/14	X (Abstract)	
107.	02049774 A2	02/20/90	JAPAN		C07D	235/28	X (Abstract)	
108.	4035455 A1	05/14/92	GERMANY		C07D	401/12	х	
109.	WO 89/03829	05/05/89	WIPO		C07D	401/12	х	
110.	0484265 A1	05/06/92	EPO		C07D	401/12	х	
111.	WO 92/08716	05/29/92	WIPO		C07D	401/12	X (Abstract)	
112.	WO 93/21920	11/11/93	WIPO		A61K	31/44	х	
113.	WO 94/02141	02/03/94	WIPO		A61K	31/44	х	
· 114.	0585722 A1	03/09/94	EPO	• •	A61K	31/44	х	
115.	06096581	04/08/94	JAPAN		G11C	114/01	X (Abstract)	
116.	06316573	11/15/94	JAPAN		C07D	401/12	X (Abstract)	
117.	WO 94/27988	12/08/94	WIPO		C07D	401/12	х	
118.	WO 95/01783	01/19/95	WIPO		A61K	9/24	х	
119.	WO 95/01977	01/19/95	WIPO		C07D	401/12	х	
120.	WO 95/18612	07/13/95	WIPO		A61K	31/44	x	
121.	wo	12/07/95	WIPO		C07D	401/12	Х	

FORM PTO-1449 Par LIST OF D	Attorney Docket Number  5573-115IP7CT3  5573-115 IP7CT7			Serial No. To Be Assigned					
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				Applicants	: Whittle et	al.	<del></del>		
<del></del>		7		Filing Date	Concurren	tly herewith	Group: N vet known		
	95/32957								
122.		01/25/96	WIPO		A61K	9/24	X		
123.	WO 96/01623	01/25/96	WIPO		A61K	9/26	x		
124.	WO 96/02535	02/01/97	WIPO		C07D	401/12	х		
		FOREIGN	PATENT DOCU	JMENTS (Con	nt'd.)	<del>-,</del>			
	Document Number	Date	Cou	ıntry	Class	Subclass	Translation Yes   No		
125.	WO 97/20851	06/12/97	WIPO		C07F	7/08	X		
126.	WO 97/25030	07/17/97	WIPO		A61K	9/46	х		
127.	WO 98/19668	05/14/98	WIPO		A61K	9/50	х		
128.	WO 98/53803	12/03/98	WIPO		A61K	9/28	х		
129.	WO 98/54171	12/03/98	WIPO		C07D	401/12	х		
130.	WO 99/08500	02/25/99	WIPO		NONE		х		
	OTHER DOC	UMENTS (Ir	ncluding Author,	Title, Date, Pe	rtinent Pages	Etc.)			
131.		n of Action o	f the Gastric Acid				al of Medicinal		
132.	Beckett et al.; "4 Pharmacol 8:66	l-Hydroxyber 1-665 (1956)	nzazoles: Prepara	tion and Antib	acterial Activ	ities," <i>J. Phar</i>	m. and		
133.	Brändström et a Journal of Gasti	Brändström et al.; "Structure activity relationships of substituted benzimidazoles," Scandinavian Journal of Gastroenterology 20:Supplemental 108 15-22 (1985).							
134.	Brändström et al Chemical Transf (1989).	.; "Chemical	Reactions of Om	eprazole and C	)menrazole A	nalogues. I. A	Survey of the <i>ica</i> 43:536-548		
135.	Brändström et al Reaction of Ome 568 (1989).	.; "Chemical prazole in the	Reactions of Om Presence of 2-N	eprazole and C Mercaptoethanc	meprazole A	nalogues. II. F	Kinetics of the avica 43:549-		
136.	Brändström et al Behaviour of Co	; "Chemical I	Reactions of Om- ne Omeprazole S	eprazole and O ystem," Acta C	meprazole A Chemica Scan	nalogues. III.	Protolytic 69-576 (1989)		

Pate	U.S. Department of Commerce ent and Trademark Office	Attorney Docket Number -5573-1151P7CT3- 5573-115 IP7C77	Serial No. To Be Assigned				
LIST OF DO	OCUMENTS CITED BY APPLICANT	373-713 177277	Lisightu				
(U	se several sheets if necessary)						
		Applicants: Whittle et al.					
		Filing Date Concurrently herewith	Group: Not				
137.	Brändström et al.; "Chemical Reactions of O Compounds of the Omeprazole System with 586 (1989).	meprazole and Omeprazole Analogues. IV. 2-Mercaptoethanol," Acta Chemica Scandin	Reactions of mavica 43:577-				
138.	Brändström et al.; "Chemical Reactions of O N-Alkylated Derivatives of Omeprazole Ana Scandinavica 43:587-594 (1989).	meprazole and Omeprazole Analogues. V. logues with 2-Mercaptoethanol," Acta Cher	The Reaction of				
139.	Brändström et al.; "Chemical Reactions of One of Omeprazole in the Absence of 2-Mercapto	meprazole and Omeprazole Analogues. VI. sethanol," Acta Chemica Scandinavica 43:5	The Reactions 95-611 (1989)				
140.	Clissold et al.; "Omeprazole A Preliminary R Properties, and Therapeutic Potential in Pepti 32:15-47 (1986).	eview of its Pharmacodynamic and Pharma	cokinetic				
	OTHER DOCUMENTS (Including Author, Titl	e, Date, Pertinent Pages, Etc.) (Cont'd)					
141.	Erlandsson; "Resolution of the enantiomers of chromatography on a trisphenylcarbomoylcel enantiomers of omeprazole on gastric glands,	f omeprazole and some of its analogues by lulose-based stationary phase. The effect of	`the				
. 142.	Lindberg et al.; "Structure-activity relationships of omeprazole analogues and their mechanism of action," TIPS 8:399-402 (October 1987).						
143.	Maier et al.; "Diphenylethanediamine (DPED 3,5-Dinitrobenzoylated (S,S)- and (S,R)-DPE Standard (R)-Phenylglycine-Derived Phase in	DA-Derived Chiral Stationary Phases with	Pirkle's				
144.	Marle et al.; "Separation of enantiomers using Journal of Chromatography 582:233-248 (19	cellulase (CBH I) silica as a chiral stationa					
145.	Marle et al.; "Chiral stationary phases based of on silica," Journal of Chromatography 648:3:	on intact and fragmented cellobiohydrolase is 33-347 (1993).	I immobilized				
. 146.	Ohishi et al.; "Structure of 5-Methoxy-2-{[4-n benzimidazole (Omeprazole)," Acta Cryst. C4	nethoxy-3,5-dimethyl-2-pyridinyl)methyl]sı 15:1921-1923 (1989).	ulfinyl}-1 <i>H</i> -				
147.	Sachs et al.; "Gastric H,K-ATPase as Therape (1988).	· · · · · · · · · · · · · · · · · · ·	<i>l.</i> <b>28</b> :269-284				
148.	Uray et al.; "Diphenylethanediamine derivatives as chiral selectors VIII. Influence of the second amid function on the high-performance liquid chromatographic enantioseparation characteristics of (N-3,5-dinitrobenzoyl)-diphenylethanediamine based chiral stationary phases," Journal of Chromatography 7799:1+2 67-81 (March 1998)						
149.	von Unge et al.; "Stereochemical assignment of fenchyloxymethyl derivative of (+)-(R)-omepr	of the enantiomers of omeprazole from X-ra azole," Tetrahedron: Asymmetry 8:12 1967	y analysis of a 7-1970 (1997).				
150.	U.S. Patent Application No. 09/629,587 to WI July 31, 2000.						
151.	U.S Patent Application No. 09/628,840 to Wh filed July 31, 2000.	ittle, et al. entitled Method of Improving Bio	oavailability;				

FORM PTO-1449 Pate	U.S. Department of Commerce ent and Trademark Office	Attorney Docket Number -5573-115IP7CT3- 5573-115IP7CT 7	Serial No. To Be
LIST OF DO	OCUMENTS CITED BY APPLICANT	373-715177217	Assigned
(U	se several sheets if necessary)		
		Applicants: Whittle et al.	
· · · · · · · · · · · · · · · · · · ·		Filing Date Concurrently herewith	Group: N t
152.	U.S. Patent Application No. 09/629,634 to filed July 31, 2000.	o Whittle, et al. entitled Pharmaceutical Unit I	Dosage Form;
153.	U.S. Patent Application No. 09/645,148 to Dosage Form; filed August 24, 2000.	o Whittle, et al. entitled Dry Blend Pharmaceu	tical Unit